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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,520	10/14/2005	Dale Lesley Bodian	4-33178A	4677

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NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.  
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CAMBRIDGE, MA 02139

EXAMINER
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DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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01/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/553,520	Applicant(s) BODIAN ET AL.	
	Examiner Jennifer Dunston	Art Unit 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### DETAILED ACTION

Claims 1-48 are pending in the instant application.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 11-16, drawn to a method for identifying a nucleic acid or protein associated with osteoarthritis (OA), comprising detecting expression by a transfected cell of one or more marker nucleic acids.

Group II, claim(s) 7-10 and 17-20, drawn to a method for identifying a nucleic acid or protein associated with OA, comprising detecting expression by a transfected cell of one or more marker polypeptides.

Group III, claim(s) 21-26, drawn to a method for identifying a nucleic acid or protein associated with OA, comprising detecting proliferation of a transfected cell.

Group IV, claim(s) 27, drawn to a method for identifying an individual having OA, comprising detecting a candidate gene or gene product in cartilage or chondrocyte cells from an individual, said candidate gene or gene product being a gene or gene product set forth in Table V or VI;

Group V, claim(s) 28-30, drawn to a method for identifying a compound that may be used to treat, prevent or ameliorate OA, comprising contacting a test compound to a cell and detecting expression by the cell of a candidate gene or gene product set forth in Table V or VI.

Group VI, claim(s) 31-40, 46 and 47, drawn to a method for treating, preventing, or ameliorating OA, comprising administering a compound that modulates one or more candidate genes selected from the group consisting of those disclosed in Table V and Table VI; and a method of treating, preventing or ameliorating OA, comprising assaying a subject for levels for any one or more candidate genes or gene products selected from those disclosed in Table V and Table VI, and

administering to a subject with increased levels relative to controls a modulator of one or more candidate genes.

Group VII, claim(s) 41-45, drawn to a pharmaceutical composition to treat OA, where the composition modulates one or more candidate genes selected from those disclosed in Table V and Table VI.

Groups VIII-LXXVII, claim(s) 48 (in part), drawn to a kit comprising a polynucleotide of a candidate gene, a fragment thereof, or a complement thereof for a gene, where the gene is selected from Table V or VI. The group numbers correspond to the sequential listing of 63 genes in Table V and 7 genes in Table VI.

Group LXXVIII-CXLVII, claim(s) 48 (in part), drawn to a kit comprising an expression product of a candidate gene, or a fragment thereof, where the gene is selected from Table V or VI. The group numbers correspond to the sequential listing of 63 genes in Table V and 7 genes in Table VI.

Group CXLVIII-CCXVII, claim(s) 48 (in part), drawn to a kit comprising an antibody to an expression product of a gene disclosed in Table V or Table VI. The group numbers correspond to the sequential listing of 63 genes in Table V and 7 genes in Table VI.

The inventions listed as Groups I-CCXVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-CCXVII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a method of identifying a nucleic acid molecule associated with osteoarthritis, comprising transfecting a cell with a nucleic acid so that the nucleic acid is expressed by the cell, and detecting expression by the cell of one or more marker nucleic acids, each of said one or more marker nucleic acids being associated with OA, where expression of the one or more marker nucleic acids by the cell identifies the nucleic acid transfected into the cell as a nucleic acid associated with OA, which is shown by Liew et al (US Patent Application Publication No. 2004/0037841; e.g., paragraphs [003]-[0303]) to lack novelty or inventive step. Therefore, the technical feature does not make a contribution over the prior art and does not constitute a special technical feature.

Accordingly, Groups I-CCXVII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention for Groups IV and V. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: one gene/gene product or one combination of genes/gene products selected from Tables V and VI (for example, see claims 27 and 28).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claim 27 (Group IV), and claim 28 (Group V).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) and Section (f)(i)(B)(1) of Annex B of the PCT Administrative instructions, all alternatives of a Markush-type group must have a common property or activity and a common structure. The nucleic acid sequences and encoded proteins of the abovementioned claims each have a different chemical structure and do not share a common structure. Since the polynucleotides and proteins are not homologous over their entire length, they fail to share a common structure, i.e. a significant structural element.

The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. The peptide bonded structure of the proteins cannot be considered a significant structural element, since it is shared by all proteins. Therefore, the polynucleotide molecules and gene products do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. Upon election of any group that contains any of the aforementioned claims, Applicant is required to elect one of the members of the group set forth in the claim (i.e., one gene/gene product or a combination of genes/gene products; the elected gene(s) and protein(s) encoded thereby will be examined together).

This application contains claims directed to more than one species of the generic invention for Groups VI and VII. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(A) one gene or one combination of genes selected from Tables V and VI (for example, claims 31, 36, 41, 46 and 47); and

(B) one substance type (for example, one type of molecule from claims 34, 35, 39, 40, 44, and 45).

Applicant is required, in reply to this action, to elect a single species (which is a gene or gene combination and a substance type) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

The following claim(s) are generic: claims 31, 36, 46 and 47 (Group VI), and claim 41 (Group VII).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) and Section (f)(i)(B)(1) of Annex B of the PCT Administrative instructions, all alternatives of a Markush-type group must have a common property or activity and a common structure. The nucleic acid sequences and substance types of the abovementioned claims each have a different chemical structure and do not share a common structure. Since the polynucleotides are not homologous over their entire length, they fail to share a common structure, i.e. a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. The substance types do not share a significant common structural element and are grouped as follows based upon structure: (i) antisense oligonucleotides, (ii) triple helix DNA, (iii) RNA aptamers, (iii) siRNA, (iv) antibody or fragment thereof. Single and double stranded RNA will be examined if a specific type of single or double stranded RNA is elected. Accordingly, the genes and substance types do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. Upon election of any group that contains any of the aforementioned claims, Applicant is required to elect one species (i.e., one gene or a combination of genes, and one substance type).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Rejoinder Practice***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.  
Examiner  
Art Unit 1636

/JD/

/Joseph Woitach/  
Joseph Woitach  
SPE 1636